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MEDICAL SYSTEMS

K123708

8. 510(K) Summary [807.92]

APR 1 0 2013

The following Special 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

Manufacturer Information

Name & Address	Paramed Srl Corso Perrone 73R 16152 Genova, Italy
Submitted by:	Luca Vescovo, Authorized officer
Establishment Reg. #	3004994584

807.92(a)(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

Submitter Information

Correspondent:	Richard Olson, Correspondent USA Paramed Medical Systems, Inc 6204 W. Oakton Street Morton Grove, IL 60053 Toll Free: 1 866 840-7565 T 1 847 470-0580nF 1 847 470-0612
Contact Person	Luisella De Benedetti Paramed S.r.l. Corso F.M. Perrone 73R 16152 Genova +39 010 6489 358 luisella.debenedetti@paramed.it

Date 29/11/2012

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807.92(a)(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

Trade Name:	SPINE COIL
Common Name:	Accessory for Magnetic resonance diagnostic system
Classification Name(s):	System, Nuclear Magnetic Resonance Imaging
Classification and class of device:	21 CFR 892.1000, class II
Classification Number:	90MOS

807.92(a)(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process;

Predicate Devices

Paramed	MrOpen 0.5T	K101295

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807.92(a)(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

The proposed SPINE COIL is a surface coil aimed to the Spine district. It is characterized by the fact of being flexible. This is done to increase patient comfort.

Below the pictures of the Flexible coil (code 03-2015) and the proposed SPINE COIL are shown to give an idea of the difference.

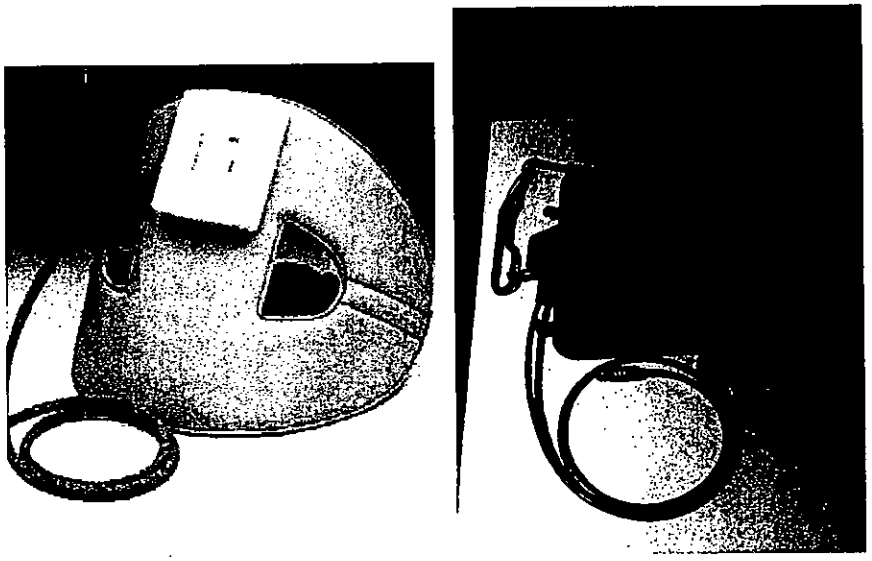

Figure 1: Flexible coil 03-2015 on the left and SPINE COIL 03-2016 on the right

Thanks to the flexible structure the proposed and the predicate coils grant patient comfort when employed in weight bearing examinations. Both coils can be used in recumbent position just as the cleared 03-2015 coil.

The significant physical and performance characteristics of the SPINE COIL are here resumed:

Examined anatomy:
Spine in all the sections

Patient positions

Recumbent

Sitting or standing

Device design

Paramed S.r.l. is a company specialized in the design of NMR Tomographs since the very beginning. The company is ISO 13485 certified since year 2006 and the Quality management System is laid down to grant overall process management including design. Written procedures are the guideline for designers who are highly specialized physicists. The Quality manager performs internal audits to grant procedures' respect. Mechanical drawings/specifications document each component being manufactured or bought.

Materials used

Paramed S.r.l. has decided to cover its devices with fire preventing ULV0 covers to minimize fire risks or damages due to external fire.

Materials contacting patient or operator are Polycarbonate and Ethylene vinyl acetate copolymer foam which are the same already employed for previously cleared devices (in the specific to Paramed's K101295 MrOpen Generic Purpose 03-2010 coil.

Cleaning procedures are the same as per the other receiving coils and are described in the User Manual.

807.92(a)(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph

Device Intended Use(s)

The intended use of the SPINE COIL is to enable the MrOpen K101295 systems designed by Paramed to perform MR scan of the human spine either in the conventional recumbent position or with the patient sitting or standing (weight-bearing). The SPINE COIL inherits the same limitations of the Tomograph. The SPINE COIL enables the MRI System to which it is applied to acquire images of the Spine in transverse, sagittal, coronal and oblique cross-sectional directions. The images which are produced correspond to spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

807.92(a)(6) If the device has the same technological characteristics(i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. [omissis]

Technological Characteristics

The SPINE COIL 03-2016 is substantially equivalent to

- Paramed MrOpen K101295 - Flexible COIL 03-2015

Technological Characteristic	SPINE COIL 03-2016	Flexible coil 03-2015 predicate K101295
Channels	4	1
Minimum SNR	55	65
Minimum SNR for each channels	40	n.a.
Examined anatomy	Spine	Spine

- Paramed MrOpen K101295 – General Purpose COIL 03-2010

Technological Characteristic	SPINE COIL 03-2016	General purpose coil 03-2010 predicate K101295
Material [outer surface]	Ethylene vinyl acetate copolymer foam	Ethylene vinyl acetate copolymer foam
Manufacturer	Leidel & Kracht	Leidel & Kracht

No new materials are in contact with the patient because:

- The new coil is manufactured employing the same materials as the predicate devices' coils (no new material)
- No contact with the skin is considered as normal use. The User Manual addresses the need to prevent coil contamination by minimizing contact of the coil with the patient's skin. No invasive use is intended, hence no contact with undamaged skin or body fluids.

Also in the event of a foreseeable misuse there is no change in the type and duration of contact with patient between the actual and predicate devices which are aimed to perform the same examinations according to the same procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2013

LUISELLA DE BENEDETTI
QUALITY MANAGER
PARAMED S.R.L.
CORSO F.M. PERRONE 73R, 16152 GENOVA
ITALY

Re: K123708
Trade/Device Name: Spine Coil 03-2016
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 11, 2013
Received: March 21, 2013

Dear Ms. De Benedetti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-

free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123708

Device Name: SPINE COIL 03-2016

Indications for Use:

The intended use of the SPINE COIL is to enable the MrOpen K101295 systems designed by Paramed to perform MR scan of the human spine either in the conventional recumbent position or with the patient sitting or standing (weight-bearing). The SPINE COIL inherits the same limitations of the Tomograph. The SPINE COIL enables the MRI System to which it is applied to acquire images of the Spine in transverse, sagittal, coronal and oblique cross-sectional directions. The images which are produced correspond to spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K123708